TEXAS
Health and Human Services

Texas Department of State Health Services

COVID-19 Vaccine Updates: Focused Review

November 4, 2020

DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

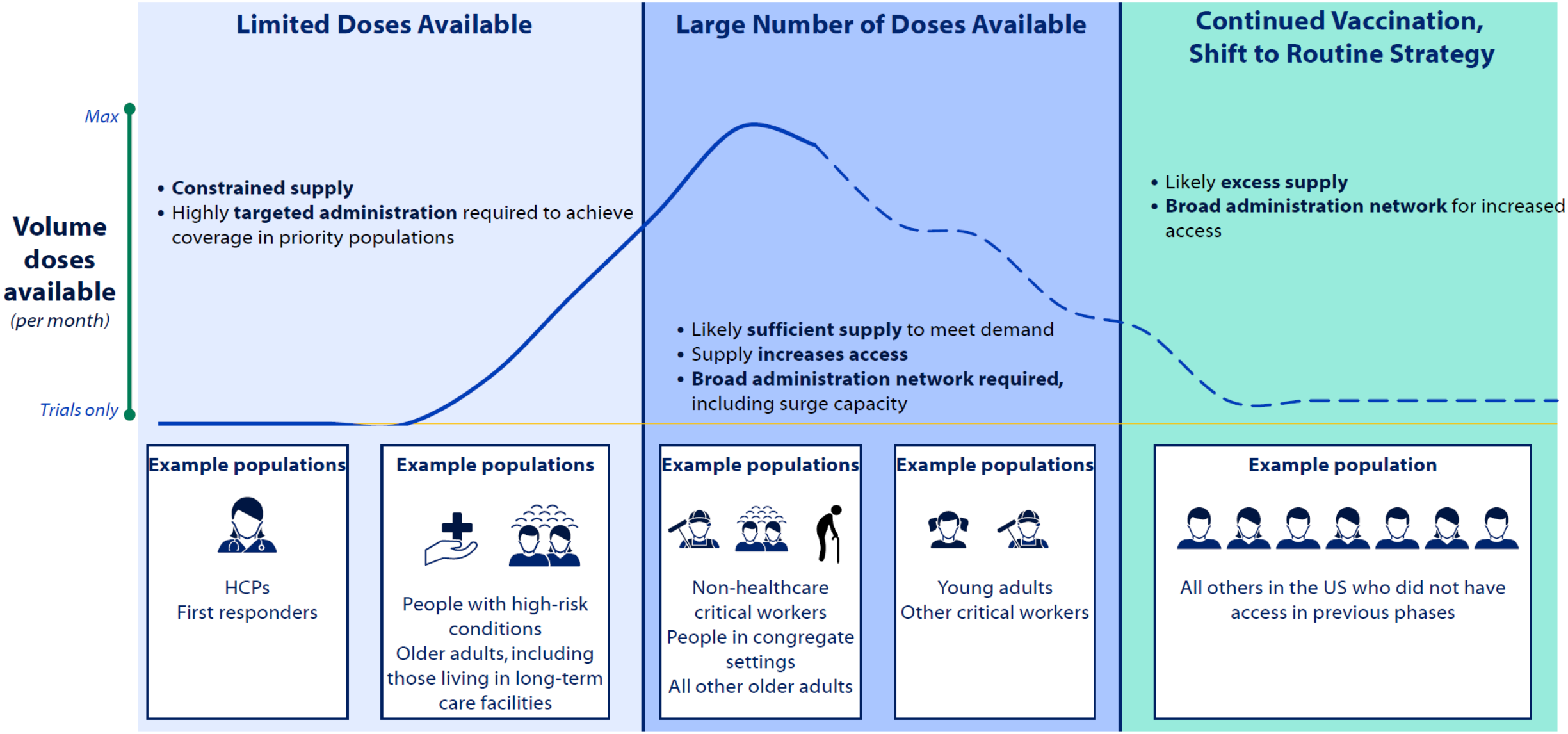
November 4, 2020

Discussion Topics

- Opening Remarks
- Vaccine Distribution
- Vaccine Landscape
- Storage, Handling & Administration
- Q&A
- Closing Remarks and Next Meeting

Illustrative scenario for planning purposes; will be adapted based on clinical / manufacturing information on all OWS candidates & vaccine prioritization

Distribution will adjust as volume of vaccine doses increases



Illustrative example populations; final prioritization to be decided by ACIP

COVID-19 Vaccine Vaccination Phased-Approach Overview

- Phase 0 (October 2020-Late November 2020)
- Phase 1 (Late November 2020 – December 2020*)
  - Limited COVID-19 Vaccine Doses Available
- Phase 2 (January 2021-July 2021*)
  - Large Number of Doses Available
  - Supply Likely to Meet Demand
- Phase 3 (July 2021 -October 2021*)
  - Sufficient Supply

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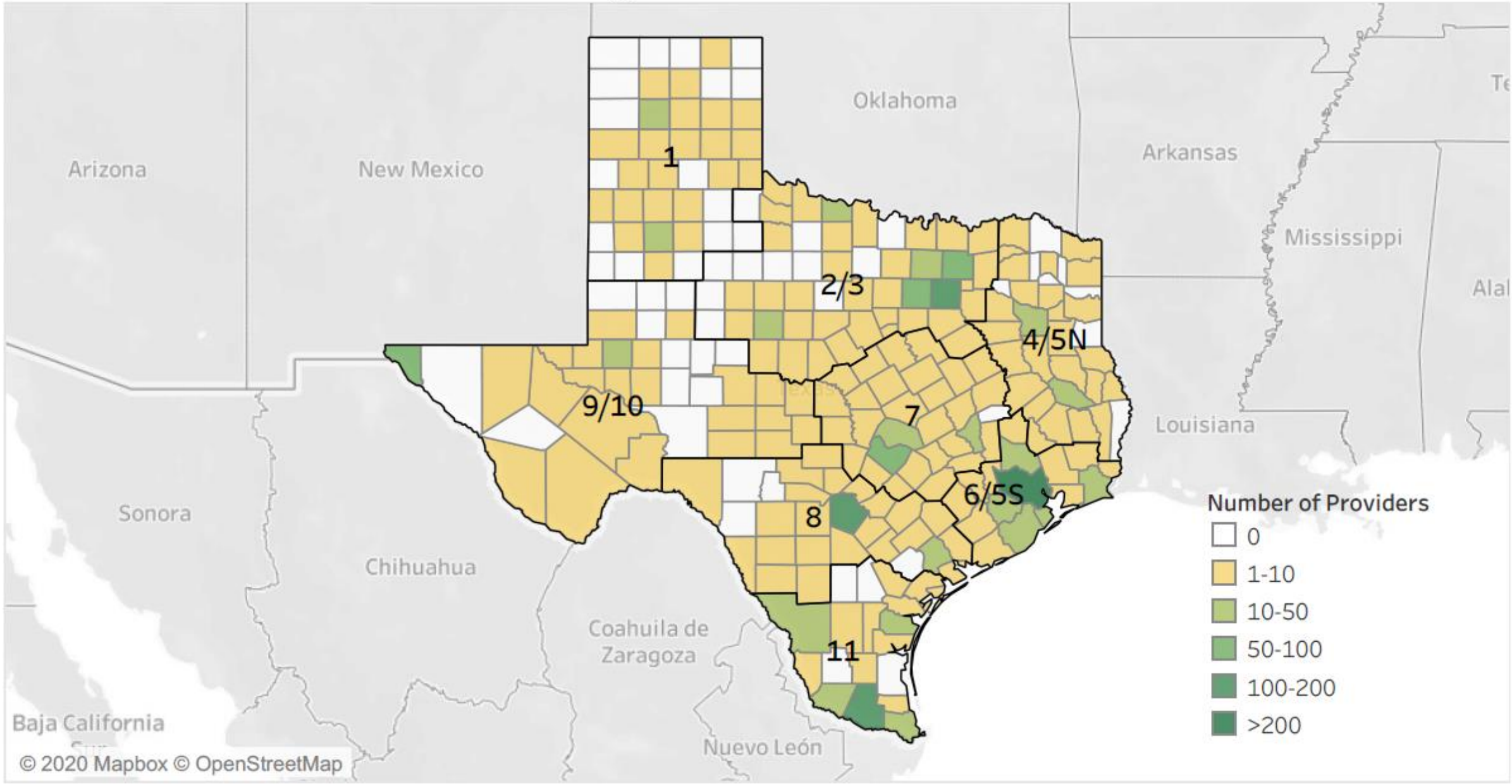
**Specific dates are subject to change.*

COVID-19 Enrolled Vaccine Providers by County



Resources

Website for Providers:
www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx

FAQ for Providers
https://www.dshs.texas.gov/immunize/covid19/COVIDproviderfaq.pdf

DSHS COVID-19 Vaccine Provider hotline:
(877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or
Email: COVID19VacEnroll@dshs.texas.gov.

Website to enroll as a COVID-19 provider:
EnrollTexasIZ.dshs.texas.gov.

General Questions:
Email: COVIDvaccineQs@dshs.texas.gov

COVID-19 Vaccine Landscape

Evolving Landscape for COVID-19 Vaccine

Key Assumptions for COVID-19 Vaccine

Limited doses may be available in December 2020, but **supply will increase substantially** in 2021

Initial supply will either be **approved as a licensed vaccine** or **authorized for use under an EUA** issued by the FDA

Cold chain storage and handling requirements are likely to vary from **refrigerated** to **ultra-cold frozen**

Two doses, separated by ≥21 or 28 days, will be **needed for immunity** for most COVID-19 vaccines

COVID-19 Vaccine Candidates

Manufacturer	Platform	Age Group	Doses needed[2]	Timing	Storage/Handling
Moderna[1]	mRNA	≥18 years	2	0, 28 days	Frozen 7 days refrigerated
Pfizer/BioNTech[1]	mRNA	≥ 12 years	2	0, 21 days	Ultra Cold Frozen 5 days refrigerated
AstraZeneca/Oxford[1]	Non-replicating Viral Vector	≥18 years	2	0, 28 days	Refrigerated
Janssen/Johnson & Johnson[1]	Non-replicating Viral Vector	≥18 years	1	N/A	Frozen 3 months refrigerated
Novavax	Recombinant Protein Subunit	≥18 years	2	0, 21 days	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated

1. Phase 3 2: Intramuscular injection

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1. Phase 3 2: Intramuscular injection

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m-RNA Vaccine Candidates

COVID-19 Vaccine Candidates (Moderna vs. Pfizer)

	moderna	Pfizer
Presentation	Multidose vials (10 doses/vial)	Multidose vials (5 doses/vial)
Reconstitution	No	Yes, with saline
Dose	100 mcg IM	30 mcg IM
2-Dose Series	Day 0 & Day 28	Day 0 & Day 21
Storage	Frozen: 6 months Refrigerator: 7 days Room Temp: 12 hours	Ultra-cold frozen: 6 months Refrigerator: 5 days Room Temp: 6 hours
Minimum Doses Order	100 (10 vials)	975 doses (195 vials)
Availability by end of 2020	~20 Million	~100 Million
Study Status		
Enrollment	Complete (total 30,000) 2nd dose: 25,654	43,249 (total 44,000) 2nd dose: 37,006
Age Groups	≥18 years of age (25%_participants are ≥ 65 years)	**≥12 years of age** (46%_participants are ages 56-85 years)
Safety Analysis for EUA	Post second dose 2-month median safety data	
	Second half of November	Not available
Efficacy for EUA	**Interim Analyses #1**	
	53 cases (74% VE)	32 cases (79% VE)

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Storage, Handling & Administration

Pfizer/BioNTech BNT162b2

Ultra-Cold Frozen

Product Packaging Overview

1 Primary Packaging

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 5 doses per vial after dilution

2 Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 975 doses per tray
- A smaller tray, containing 25 vials (125 doses) is in development with estimated availability in early 2021

3 Tertiary Container: Thermal Shipper

Item	Description
1	Dry Ice Pod
2	Payload (Vial Trays)
3	Inner Lid
4	Payload Sleeve
5	Outer Carton

- Minimum 1 tray (975 doses) or up to 5 trays (4875 doses) stacked in a payload area of the shipper
- Payload carton submerged in dry ice pellets
- Thermal shipper keeps ULT (-75±15°C) up to 10 days if stored at 15°C to 25°C temperatures without opening.
- Thermal shippers are reusable and designed to be a temporary storage containers by replenishing dry ice

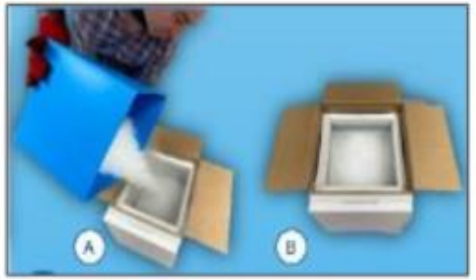
Vaccine Storage Options* At the Point of Vaccination

1 Ultra-Low Temperature Freezer

- Store as frozen liquid at -75°C±15°C for long term storage.
  - Emergency Use vials are labeled as -70°C±10°C, however they can be safely stored in a freezer set to the USP condition of -75°C±15°C
- Frozen vials at have a 6 month expiry from the date of manufacture
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)

2 Thermal Shipper Designed for Temporary Storage



- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper should be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice temperature monitor

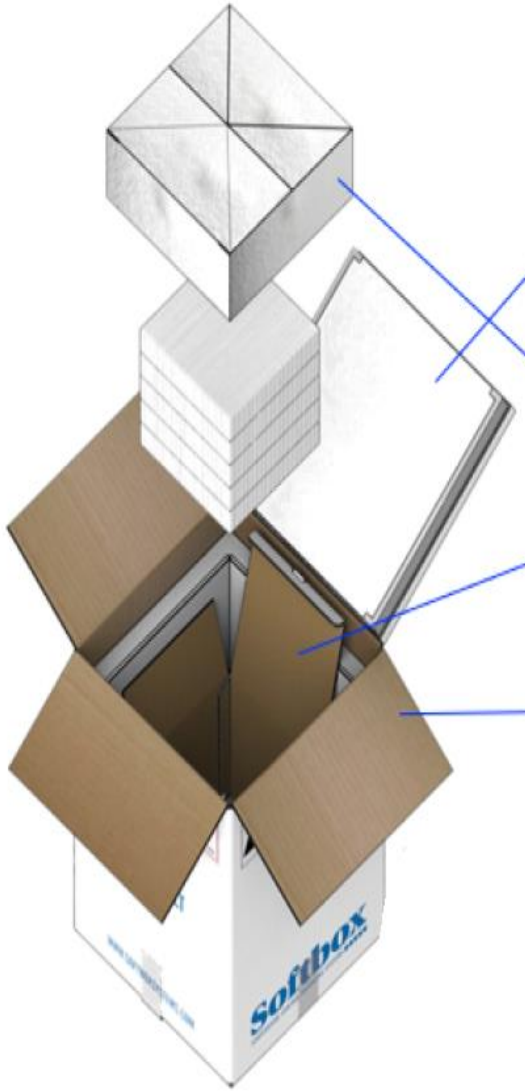
3 2 to 8°C Refrigerator

- Can be stored at 2 to 8°C up to 5 days
- Room temperature storage is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

*Product temperature must always be monitored to ensure adherence to temperature requirements for different storage conditions are being met in alignment with site Standard Operating Procedures.

Please note that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements, but this deck reflects the Company's current understanding based on the totality of available data currently. Current as of September 8, 2020.

Ultra Low Temperature Thermal Shipper – Overview of Pack Out



ITEM	DESCRIPTION
1	VIP LID
2	DRY ICE POD
3	PAYLOAD SLEEVE (Takes 1 to 5 vial trays)
4	MEDIUM ULT THERMAL SHIPPER

Softbox Medium ULT Weights and Dimension	
Empty Shipper Weight	8.5 kgs
Available Payload Space	9.65" x 9.65" x 9.49"
External Dimension	15.75" x 15.75" x 22.04"
Amount of Dry Ice	23 kgs
Tare Weight w/ Dry Ice	31.5 kgs
Total Weight w/ 1 Vial Tray	32.6 kgs
Total Weight w/ 5 Vial Trays	36.7 kgs

Weight of Vial Tray	1.038 kgs

ULT Shipper – Unpacking and Re-Use General Schematics

Receipt of ULT Thermal Shipper at Point of Vaccination

- Upon receipt, GPS enabled logger should be disabled by pressing the stop button on the device.
- Upon receipt, product shipments should be visually inspected to ensure all ordered quantities were received, and in good standing (no broken vials).
- Issues with the shipment should be immediately communicated to Pfizer Customer Service per agreed upon terms.

If ULT Freezer Available; Transfer Trays to ULT Freezer

- Remove Dry Ice Pod from shipper.
- Take out Vial Tray(s) from Payload Sleeve and transfer to ULT Freezer.
- Transfer of product from the thermal shipper must be done in less than 5 minutes to prevent premature product thawing.

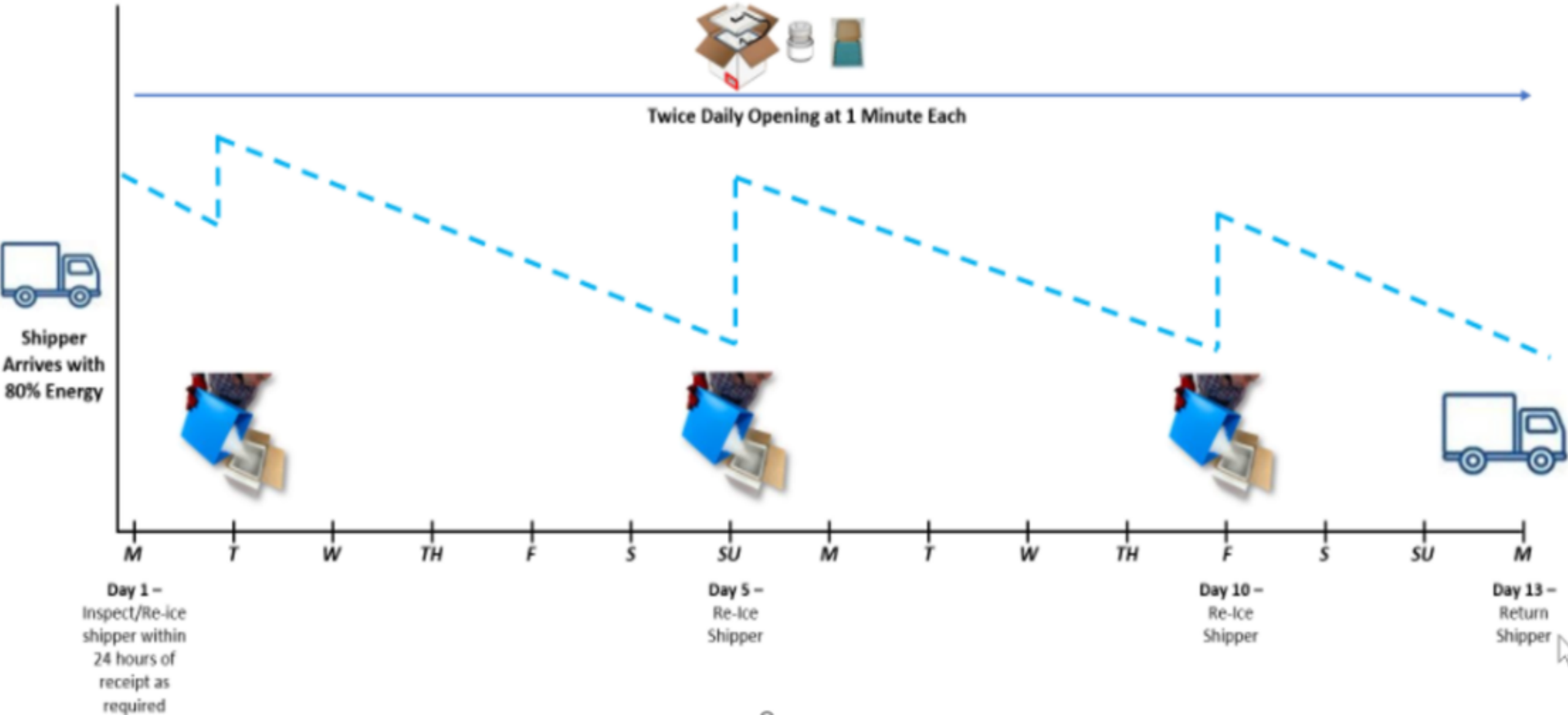
If Thermal Shipper is Used for Temporary Storage; Replenish Dry Ice in Thermal Shipper in 24 hours of Delivery

- Dispense Dry Ice Pellets into shipper per re-icing instructions provided.
- Close the lid and ensure that the box is sealed appropriately.
- Add additional dry ice every five days accordingly.

Diminishing Shipper Energy with Use Over Time

Handling instructions to vaccination centers

- Inspect/Re-ice shipper within 24 hours of receipt as needed as part of goods receipt process
- Re-ice every 5 days (Up to 3 times)
- Return the shipper within 10 business days



Vaccine Preparation and Administration

Point Of Use (POU)

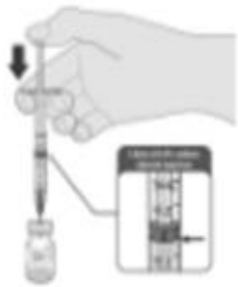
Removing the Vials to Thaw

From storage, **remove 1 vial for every 5 recipients** according to planned vaccinations schedule.

Vials may be stored in the refrigerator for 5 days (120 hours).

Dilute the Vaccine

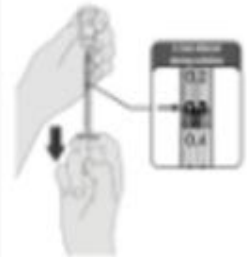
Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent
Do not use any alternate diluents.



Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.

Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

Preparing the Dose



Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.

For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

Vaccine Administration

Pfizer BioNTech COVID-19 Vaccine 30 mcg/0.3 mL

Diluted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).

A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.

21 DAYS

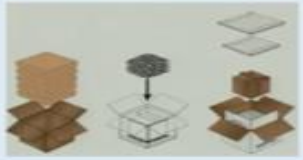
Possible Vaccine Availability Under EUA

Candidate	November 2020	December 2020 - March 2021	End of December 2021
Vaccine A	• The goal is to submit to the FDA late November to request EUA. • Vaccine being produced concurrently with Phase 3 clinical trials.	Goal is to have 100 Million doses	Goal is to have 1.3 Billion doses

Vaccine Packaging Overview

- 2ml type 1 glass preservative fee multi-dose vial (MDV)
- Each MDV has **0.45ml frozen liquid vaccine product**
- 5 doses per vial

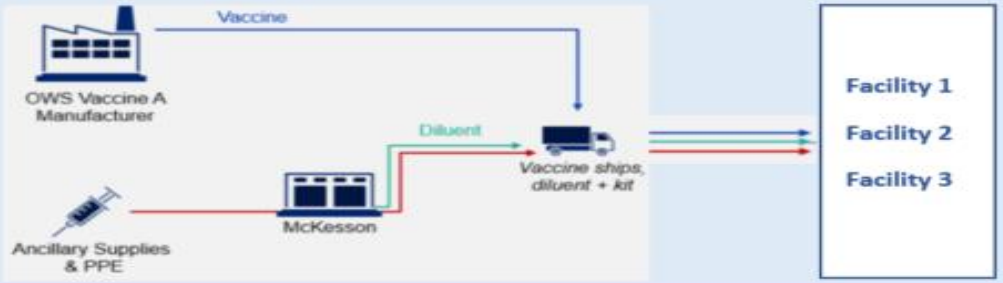
- Single tray ("Pizza Box") holds 195 vials
- 975 doses per tray
- Tray (white Box) 229 x 229x40mm



- Minimum 1 tray (975 doses) or up to 5 trays (max 4875) stacked in a payload carton
- Payload carton submerged in 23 Kg dry ice pellets (10 mm-16 mm pellets)
- Thermal shipper ("Pizza Box") dimensions
  - Internal: 245mmx245mmx241mm
  - External: 400mmx400mmx560mm
- Total weight of the thermal shipper - 35 kg

Vaccine/Diluent/Ancillary Supplies/PPE Shipment

Minimum order: ~1.000 doses
Maximum order: ~5,000 doses



Vaccine Storage & Handling at the Point of Vaccination

Ultra-Low Temperature Freezer

- Can be stored at -70°C ± 10°C for 6 months

Thermal Shipper

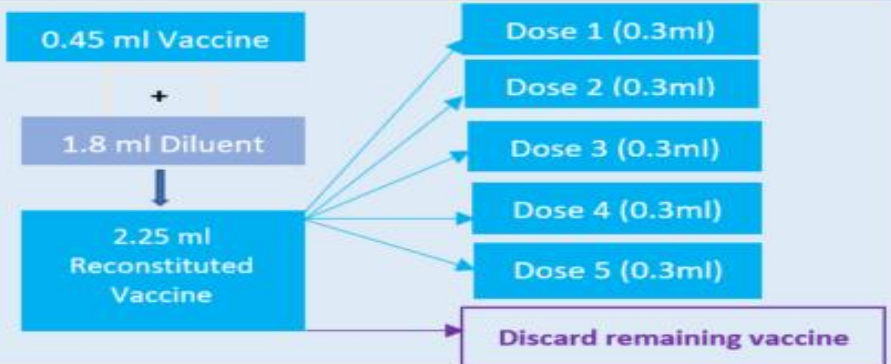
- **Must replenish dry ice within 24 hours of receiving shipment and again on day 5 & 10.**
- **The Pizza Box must only be opened twice per day and should be closed within 1 minute (or less) of opening.**
- The shipper delivered with Real Time Monitoring (RTM) temperature logger, GPS enabled. This will be activated from the manufacturer to point of vaccination. It will then be disconnected.
- The thermal shipper will need to be returned to the manufacturer within 13 days.

The Vaccine

- Vaccine can be taken out of the tray (Pizza Box) and stored in refrigerator (at 2-8°C) and must be used within **5 days** (discard unused doses after 5 days). **This is the vaccine straight from the box that is NOT reconstituted.**
- **Once the vaccine is reconstituted using the diluent, it can be stored at room temperature (RT) and must be used within 6 hours** (discard unused, reconstituted vaccine after 6 hours).

Vaccine Administration

1. **Take the vaccine vial (0.45ml) out of the Pizza Box or refrigerator**
   - Let it thaw for 30 mins at room temperature
   - Gently invert the vaccine vial 10 times to homogenize the content
2. **Draw 1.8 ml of the provided Diluent** (saline provided in 3m vial) **and combine it with the vaccine**
   - Use 3 ml syringe/23-gauge needle
   - Invert 10 times again
3. **Draw 0.3 ml (one dose) of the reconstituted vaccine**
   - (using 1 ml syringe/21-23gauge needle)
   - **Total of 5 doses** in each reconstituted vial
4. **Administer by intramuscular injection (IM) to 5 individuals (must be done within 6 hours)**
5. **Discard any remaining liquid in the vial**



Pfizer/BioNTech BNT162b2 Vaccine
CDC Guidance

- The CDC does not recommend transporting vaccine at ultra-cold temperatures.
- However, the vaccine can be kept for 5 days (120 hours) between 2 and 8°C.
  - The amount needed to conduct off-site clinics may be removed, stored, and transported following guidance for vaccines stored between 2°C and 8°C.
- CDC's Vaccine Storage and Handling Toolkit is being updated to provide detailed guidance and key considerations.

Moderna mRNA-1273

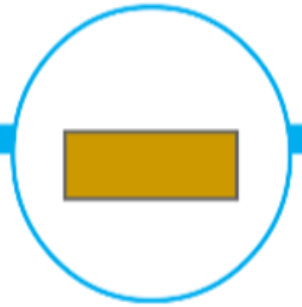
Frozen

mRNA-1273 from manufacturing to distribution

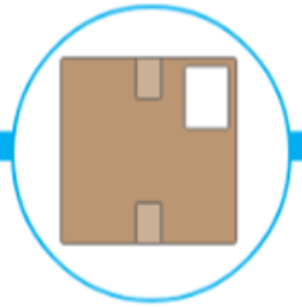
Pre-conditioned
-25 to -15°C/-13-5°F shipper

-25 to -15°C Temp controlled truck for full loads

Multi-dose vial
(10 preservative free, 0.5 mL doses per vial)



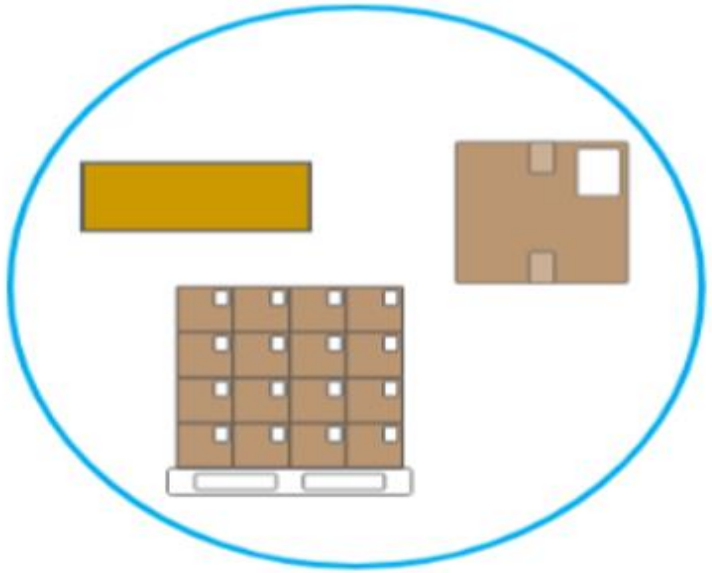
10-vial cartons
(100 doses)



Full cases
(1,200 doses)

Full or partial pallets
(up to 230,400 doses)

mRNA-1273 Distribution



Ship any configuration using existing infrastructure

Storage Conditions for a non-punctured vial

Freezer: -25 to-15°C/-13 to 5°F for 6 months

+

Refrigerator: 2-8°C/ ~36-46°F for up to 7 days. Do not refreeze

+

Room temperature: up to 12 hours

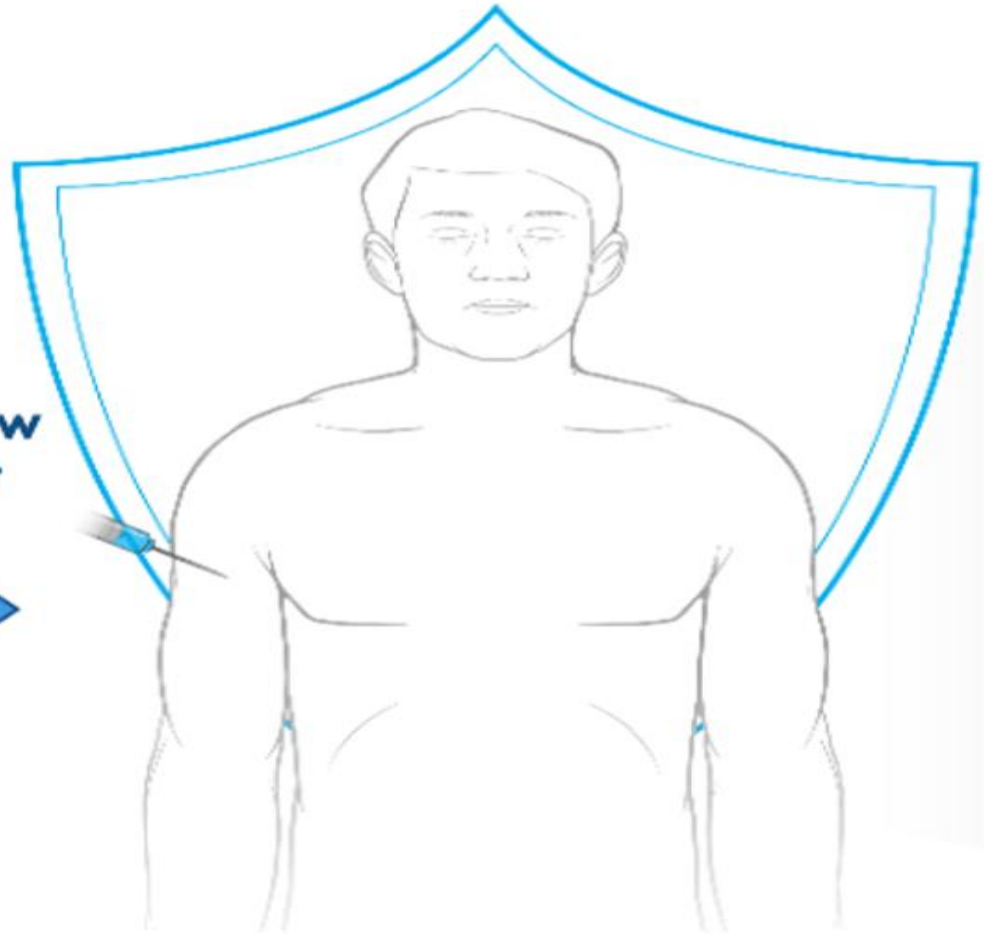
Each vial of mRNA-1273 has 10, 0.5 mL doses

Standard needles & syringes

No dilution required

10 dose vials

Ready to use, draw 0.5mL and inject intramuscularly



REMINDER

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November 4, 2020

Q&A

Closing Remarks & Next Meeting: Nov 10, 11 AM CST